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1633

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/607,752

Applicant(s)

DELCAYRE, ALAIN

Examiner

Maria B. Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-8, 11 and 13-28 is/are pending in the application.
- 4a) Of the above claim(s) 3-8, 11, 13 and 16-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14 and 24-28 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/30/03.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 10/05.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to a response to a restriction requirement filed 8/18/05. Claims 1, 2, 9, 10 and 12 have been cancelled. Claims 14, 17, 22 and 23 have been amended. Claims 24-28 have been added. Claims 3-8, 11 and 13-28 are pending in this application. Claims 3-8, 11, 13 and 16 have been withdrawn. Therefore, claims 14, 15 and 17-28 are under examination in this application.

Election/Restrictions

While applicants elected without traverse Group I (claims 1, 2, 9, 10, 12, 14 and 15) in the amendment filed 8/18/05, applicants have cancelled all claims drawn to pending subject matter and added new claims drawn to new subject matter. Applicants have argued in the response filed 8/18/05 that newly added claim 24 is drawn to subject matter previously recited in claims 9 and 10.

This is not found persuasive because Group I in the restriction requirement made 7/15/05 was drawn to a polypeptide of SEQ ID NO:61-77, which are peptide epitopes from *Mycobacterium vaccae*. Newly added claims 24-28 are drawn to a fusion protein comprising SEQ ID NO:116, which is a fusion protein, comprised of multiple epitopes identified from *Mycobacterium vaccae*. Therefore, applicants have cancelled pending elected subject matter and elected subject matter that was not so treated in the restriction requirement filed 7/15/05. Hence, the original restriction requirement is moot and the following new restriction requirement has been made of pending claims 3-8, 11 and 13-28.

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 3-8, 11, 13 and 16, drawn to a polynucleotide comprising a nucleic acid selected from the group consisting of SEQ ID NOs: 8-21, classified in class 435, subclass 320.1.
- II. Claims 14, 15, 24-28, drawn to a fusion polypeptide comprising SEQ ID NO: 116, classified in class 530, subclass 350.
- III. Claims 17-21, drawn to a method for enhancing an immune response in a patient comprising administering a composition of Group II, classified in class 514, subclass 44 and class 424, subclass 168.1.
- IV. Claim 22, drawn to a method for the treatment of an immune disorder comprising administering a composition of Group II, classified in class 514, subclass 2.
- V. Claims 22-23, drawn to a method for the treatment of an infectious disease comprising administering a composition of Group II, classified in class 514, subclass 2.
- VI. Claims 22, drawn to a method for the treatment of cancer comprising administering a composition of Group II, classified in class 514, subclass 2.

The inventions are distinct each from the other because of the following reasons:

The polypeptide of Group II and polynucleotide of Group I are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct

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molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. A polypeptide of Group II can be made by methods using some, but not all, of the polynucleotides that fall within the scope of Group I, it can also be recovered from a natural source using biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of Groups I and II are patentably distinct.

Furthermore, searching the inventions of Groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides, which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers, which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of Groups I and II together.

Inventions III-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method for enhancing an immune

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response in a patient comprising administering a composition of Group II (Group III), the method of treatment of an immune disorder comprising administering a composition of Group II (Group IV), the method for the treatment of an infectious disease comprising administering a composition of Group II (Group V), and the method for the treatment of cancer comprising administering a composition of Group II (Group VI) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for each method differs significantly. The methods and material for enhancing immune responses, treating immune disorders, infectious disease and treating cancer have different purpose, different method steps and different technical consideration. For example, methods of enhancing an immune response will not necessarily led to treatment of infectious disease, immune disorders or cancer and the compositions required for enhancing an immune response are not necessarily the same as those required to treat an immune disorder or treat an infectious disease or treat cancer. Target subjects of each will necessarily differ as well as consideration of specific antigens to be injected. Thus, each of the antigens differ in properties and compositions. Therefore, each method is divergent in materials and steps. For these reasons the Inventions III-VI are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches as they are not coextensive. A search for art pertaining to methods of enhancing immune responses is not coextensive with methods for treating disorders and diseases and cancer. Furthermore, a

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method of treatment of immune disorders, infectious disease and cancer are not coextensive. As such, it would be burdensome to search the inventions of Groups III-VI together.

Inventions II and either III, IV, V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II can be used to generate antibodies for detection of *Mycobacterium*.

Searching the inventions of Groups II and either III, IV, V and VI together would impose serious search burden. The inventions of Groups II and either III, IV, V and VI have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polypeptides and the method of treatment using the polypeptide are not coextensive. Group I encompasses molecules which are claimed in regard to a reference sequence SEQ ID NO:., which are not required for the search of Group III, IV, V and VI. In contrast, the search for Group III, IV, V and VI would require a text search for the methods in addition to a sequence search. Prior art, which teaches a polypeptide that is SEQ ID NO:116 would not necessarily be applicable to the method of using the SEQ ID NO:.. Moreover, even if the polypeptide were known, the method of treatment using the product may be novel and unobvious in view of the preamble or active steps.

Inventions of Group I and III, IV, V and VI are unrelated because the product of Group I is not used or otherwise involved in the process of group III, IV, V and VI.

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Claim 22 links the inventions of Groups IV-VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claim depending from or including all the limitations of the allowable linking claims is presented in the continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See MPEP 804.01.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provision of MPEP 821.04. Process claims that depend for or otherwise include all the limitations of the patentable produce will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendment submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirements for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 USC 101, 101,

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103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claim in light of *In re Ochiai*, *In re Brouwer* and 35 USC 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 USC 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Election/Restrictions

Applicant's election **without** traverse of Group II (claims 14, 15, 24-28) drawn to a fusion polypeptide comprising SEQ ID NO:116 in the telephonic interview 10/12/05 is acknowledged. Claims 3-8, 11, 13 and 16-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim.

Information Disclosure Statement

An IDS filed 10/30/03 has been identified and the documents considered. The signed and initialed PTO Form 1449 has been mailed with this action. The document listed as 1 is an International Search Report, which is not considered to be a document under 37 CFR 1.98. Therefore, the International Search Report has been considered but has been crossed off the 1449 so that it will not appear on the face of any patent issuing from the instant application.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101, which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14, 24, 25, 26 and 28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 7, 24 and 25 of US 6,436,898.

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An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims. Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of the instant invention are generic to all that is recited in claims 1, 5, 7, 24 and 25 of US 6,436,898. That is, the cited claims of U.S. 6,436,898 anticipate and fall entirely within the scope of the rejected claims of the instant application. Specifically, both claims are drawn to a fusion protein comprising SEQ ID NO:116. SEQ ID NO:71 (claim 1) and SEQ ID NO:81 (claim 24) disclosed in U.S. 6,436,898, encompass the fusion protein of the instant invention, SEQ ID NO:116. Specifically, SEQ ID NO:81 is the sequence of a fusion protein that is the amino acid sequence of SEQ ID NO:116 plus a signal sequence. Claim 1 recites "a fusion protein comprising SEQ ID NO:71". SEQ ID NO:71 is an immunogenic epitope that is a component of both SEQ ID NO:81 and 116. And therefore, a fusion protein that comprises SEQ ID NO:71 i.e. SEQ ID NO:81 is generic to the instant claims. A fusion protein comprising SEQ ID NO:71 or 81 would also comprise the amino acid sequence of a fusion protein encoded by the polynucleotide sequence of SEQ ID NO:115.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the U.S. 6,436,898 then two different assignees would hold a patent to the claimed invention of U.S. 6,436,898, and thus improperly there would be possible harassment by multiple assignees.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is vague and indefinite in that the metes and bounds of “A fusion protein encoded by the polynucleotide” are unclear. By use of “A” it appears as if there would be more than one fusion protein encoded by the polynucleotide sequence. However, the sequence provided in SEQ ID NO:116 should be the only protein encoded by SEQ ID NO:115. Hence it is unclear if applicants intended for more than one product expected that is “encoded by the polynucleotide sequence of SEQ ID NO:115” or not.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-27 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Applicants claim a fusion protein comprising a sequence having 95% identity to SEQ ID NO: 116, which possesses the ability to stimulate proliferation or interferon-gamma (IFN- γ) secretion in T cells from individuals that have been exposed to *M. tuberculosis*.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus.

Applicants recite a genus of fusion proteins that are related by having at least 95% identity to SEQ ID NO:116. Applicants have not demonstrated the structural requirements of SEQ ID NO:116 such that a person of skill in the art would know which amino acids are absolutely required for function and which can be altered to within 95% identity to SEQ ID NO:116. Functionally any fusion peptides that vary from SEQ ID NO:116 must possess the ability to stimulate proliferation or interferon-gamma (IFN- γ) secretion in T cells from individuals that have been exposed to *M. tuberculosis*. However, applicants have only reduced to practice the instant invention with a recombinant multi-epitope that is SEQ ID NO:116 as well as the individual epitopes used to generate SEQ ID NO:116, which they demonstrate stimulate proliferation of cells and secretion of IFN- γ from the cells. Specifically, applicants have identified eight plasmids encoding immunogenic -epitopes from *Mycobacterium vaccae*, which have been demonstrated to stimulate proliferation of T-cells and IFN- γ secretion.

Mycobacterium vaccae is non-pathogenic to humans and therefore, applicants propose use of

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epitopes from this organism to enhance immune response as well as to treat infectious disorders such as tuberculosis and other mycobacterial infections in humans and domestic mammals or livestock and to treat immune system disorders. Cloned *M. vaccae* fragments were inserted into pcDNA3 vectors comprising an hGH PCR fragment (pCDNA3-hGH), which encodes the hGH signal peptide and a concatenating linker used to connect the signal peptide to the epitope. The signal peptide was used to facilitate protein secretion. Expression of these recombinant epitopes in peripheral blood mononuclear cells *in vitro* lead to proliferation of the cells and IFN- γ production from the cells (table 2 and 3). Expression in mice *in vivo* induced a reduction of CFUs.

The eight cloned epitopes were then used to generate three multi-epitope constructs assembled into single constructs in pcDNA3-hGH vectors and in pET16 vectors and are disclosed as SEQ ID NO:s 79-81 and 116 (example 4). SEQ ID NO:81 or ME/D, consists of each one of the 8 epitopes described above in a particular order. The insert of ME/D in pCDNA3-hGH was subcloned into pET16. It is not disclosed but presumed that this vector lacks the signal sequence and concatenating linker of ME/D and hence would correspond to SEQ ID NO:116 as it is described as the amino acid sequence of the ME/D fusion polypeptide minus the signal peptide and concatenating linker. In example 5, the multi-epitope constructs were used to immunize mice. Example 5 teaches that ME/D was injected intraperitoneally with recombinant ME/D (rME/D). Three weeks later, mice were challenged with *M. tuberculosis*. CFU formation in the lung and spleen was demonstrated suggesting immunization. Example 6 demonstrates subcutaneous, intraperitoneal or intramuscular injection of the recombinant fusion protein into the footpads of mice lead to lymph node and spleen cell proliferation as well as secretion of IFN-

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γ . In this example, rME/D stimulated memory T cells from mice infected with M Tuberculosis to produce large amounts of IFN- γ . PBMC cells comprising these vectors were stimulated to proliferate and secrete IFN- γ . In example 8, cynomolgus monkeys were immunized with rME/D leading to proliferation of lymphocytes. It is not completely clear whether SEQ ID NO:81 or SEQ ID NO:116 is used in these experiments as the constructs used in the examples is generically referred to as ME/D. Only in example 7 is it disclosed specifically that the epitopes contained within ME/D were expressed using pET16.

An adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of claimed nucleic acid sequences. Recombinant technology for the generation of fragments or for detecting related sequences is highly developed. However, the ability to determine *a priori* whether a fragment or related sequence can function in the recited invention is not. A particular protein sequence determines the protein's structural, and functional properties, and a predictability of a representative number of claimed polypeptide sequences that display noteworthy biological properties requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e., expectedly intolerant to modification), and detailed knowledge of the ways in which a protein's structure relates to its functional usefulness (see Tertiary structure, Protein structure prediction and Smith et al). Bowie et al (applicant provided) teach that it is essential to know the residues involved in function. For example replacing the Asp in the catalytic triad of trypsin with Asn results in a 10(4) reduction in activity (see e.g. page 1306, vol

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2, paragraph 3). Therefore, the ability to predict *a priori* which sequences that will meet a particular goal is poorly developed. In addition, by claiming any fusion protein with 95% identity to SEQ ID NO: 116 that achieve a result without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See Fiers 7. Reveb 25 USPQZd 1601 (CA FC 1993) and Regents of the Univ. Calif v. Eli Lilly & Co. 43 USPQZd 1398 (CA FC, 1997)). In the instant case, applicants have not demonstrated that variance of or deletion of any, some or all of the amino acids of the fusion peptides would result in a protein that can function similarly. Therefore, the relationship between structure and function is unclear as neither applicant nor the prior art provide structural requirements of the SEQ ID NO: 116 that are able to stimulate proliferation of T-cells and IFN- γ secretion. Furthermore, applicants have only demonstrated that they are in possession of ME/D disclosed as SEQ ID NO: 116. Ultimately this is a single species of polypeptides. Given the large size and diverse nature of the recited proteins and the inability to determine which will also possess the ability to stimulate proliferation of T-cells and IFN- γ secretion, it is concluded that the invention must be empirically determined. In an unpredictable art, the disclosure of a single species would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of the claimed genus.

Conclusion

Claims 14 and 24-28 are rejected.


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Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, PhD can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Maria B Marvich, PhD
Examiner
Art Unit 1633

October 28, 2005


DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER